DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 3, 2014

Sterilucent, Inc.
% Peter Kalkbrenner
Director of Engineering
1400 Marshall Street NE
Minneapolis, Minnesota 55413

Re: K141238
Trade/Device Name: Sterilucent Self-Contained Biological Indicator
Sterilucent Biological Indicator Monitoring System
Regulation Number: 21 CFR 880.2800
Regulation Name: Indicator/Biological Sterilization Process Indicator (21 CFR 880.2800)
Regulatory Class: Class II
Product Code: FRC
Dated: September 25, 2014
Received: October 3, 2014

Dear Mr. Kalkbrenner,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin Keith
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141238

Device Name
Sterilucent Self-Contained Biological Indicator
Sterilucent Biological Indicator Monitoring System

Indications for Use *(Describe)*
The Sterilucent Self-Contained Biological Indicator is for monitoring the efficacy of the hydrogen peroxide sterilization process in the Sterilucent PSD-85 Sterilizer Lumen and Non-Lumen cycles. It is intended for use solely in a test pack.

The Sterilucent Biological Indicator Monitoring System is intended for incubating and monitoring of the Sterilucent Self-Contained Biological Indicator.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary
for the
Sterilucent Self-Contained Biological Indicator
K141238

Owner:	Sterilucent, Inc.
Address:	1400 Marshall St. NE Minneapolis, MN 55413
Contact:	Peter R. Kalkbrenner Director of Engineering
Telephone:	612-767-3253
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Summary Date: 30 October, 2014

1. Device Name and Classification

Trade Name:	Sterilucent Self-Contained Biological Indicator Sterilucent Biological Indicator Monitoring System
Common/Usual Name:	Self-Contained Biological Indicator
Classification Name:	Sterilization Process Indicator
Device Class:	Class II
Product Code:	FRC (21 CFR 880.2800)

2. Predicate Device

STERRAD® CycleSure® 24 Biological Indicator (K102884)
Smart-Well Model 1710 EZTest Incubator (K122362)

3. Device Description

The Sterilucent Self-Contained Biological Indicator is a self-contained biological indicator (SCBI) designed for use in monitoring the efficacy of the Sterilucent PSD-85 Sterilizer Lumen and Non-Lumen cycles. The SCBI consists of *Geobacillus stearothermophilus* bacterial spores, inoculated on a stainless steel carrier, and placed into a thermoplastic vial that serves as a culture tube. A small glass ampoule containing sterile culture medium (soybean casein digest formulation) and pH color indicator (Bromocresol Purple) is also contained in the vial.

The user places the Sterilucent SCBI into the Sterilucent PSD-85 sterilizer load and initiates a sterilization cycle appropriate for the particular type of load. After cycle completion, the SCBI is retrieved and activated by breaking the glass ampoule which contains a growth media. The activated SCBI is then incubated at 60°C ± 2°C for 18 hours and monitored for any color change. The appearance of a yellow color in the media indicates bacterial growth (a failing result); no color change indicates conditions for sterilization were achieved (a passing result).

The Sterilucent Biological Indicator Monitoring System is a biological indicator incubator which monitors for the presence and condition (growth [as indicated by a yellow color in the growth media] or no-growth [as indicated by purple growth media]) of Sterilucent SCBI. When an activated Sterilucent SCBI is placed into one of the incubation cavities, the LED in front of the cavity will illuminate amber. The incubator maintains the operating temperature specifications under all potential loading conditions over the recommended incubation time. It can incubate and monitor up to ten (10) Sterilucent SCBI plus one control unit.

4. Statement of Intended Use

The Sterilucent Self-Contained Biological Indicator is for monitoring the efficacy of the sterilization process in the Sterilucent PSD-85 Hydrogen Peroxide Sterilizer Lumen and Non-Lumen cycles. It is intended for use solely in a test pack.

The Sterilucent Biological Indicator Monitoring System is intended for incubating and monitoring of the Sterilucent Self-Contained Biological Indicator.

5. Technological Characteristics Summary Comparison

The Sterilucent SCBI technological characteristics are substantially equivalent to the predicate device as summarized in the table below. Both are used to monitor vaporized H_2O_2 (VHP) sterilization cycles. Each include at least 10^6 spores of *Geobacillus sterathermophilus* (the most resistant organism for vaporized hydrogen peroxide sterilization), a chemical process indicator appropriate for VHP sterilization to indicate exposure, and a glass ampoule containing soybean casein digest broth with Bromocresol Purple as the color change indicator. The carrier and culture media for both devices are packaged in a polypropylene culture tube with a polypropylene cap.

Summary of Technological Characteristics of the Device Compared to the Predicate Device

Characteristic	**New Device** Sterilucent Self-Contained Biological Indicator	**Predicate Device** CycleSure® 24 Biological Indicator
Device Design	Disc containing indicator organism, glass ampoule containing nutrient growth medium, vial containing the disc and vial, cap and liner closing the vial, and a chemical indicator in the cap.	Same
Materials of Construction	Glass (ampoule) and polypropylene (vial and cap)	Same
Indicator Organism	*Geobacillus sterathermophilus*	Same
Population	$\geq 1.0 \times 10^6$	Same
Sterilization Modality	Vaporized Hydrogen Peroxide (VHP)	Same
Indications for Use	The Sterilucent Self-Contained Biological Indicator is for monitoring the efficacy of the sterilization process in the Sterilucent PSD-85 Hydrogen Peroxide Sterilizer Lumen and Non-Lumen cycles.	The STERRAD® CYCLESURE® 24 Biological Indicator is intended to be used as a standard method for frequent monitoring of STERRAD® Sterilization cycles.

6. Summary of Non-Clinical Performance Data

Following the recommendations and guidelines in the *Guidance for Industry and FDA Staff - Biological Indicator (BI) Premarket Notification [510(k)] Submissions* (October 4, 2007), the Sterilucent SCBI was evaluated for spore population, resistance characteristics, carrier and primary packaging materials evaluation (Growth Inhibition Studies), holding time assessment, incubation time validation (Reduced Incubation Time). The results of all studies met the established acceptance criteria when applicable.

Spore population and stability was demonstrated by regularly scheduled population assays on multiple lots throughout the 24 month claimed shelf life period.

Resistance characteristics were demonstrated by regularly scheduled D-value determinations in accordance with ANSI/AAMI/ISO 11138-1 on multiple lots throughout the 24 month claimed shelf life period.

The growth inhibition studies demonstrated that, following a worst case vaporized hydrogen peroxide exposure in the Sterilucent PSD-85 Hydrogen Peroxide Sterilizer, all exposed carriers and packaging components were not bacteriostatic.

The holding time assessment study demonstrated, through a series of sub-lethal exposures and population assays, that the resistance characteristics of the Sterilucent SCBI are not altered significantly over a 29 hour hold time prior to incubation.

The RIT validation was conducted in accordance with the Guidance for Industry and FDA Staff - Biological Indicator (BI) Premarket Notification [510(k)] Submissions. The data generated supports an incubation time of 18 hours.

Additionally, performance characterization in the Sterilucent PSD-85 Hydrogen Peroxide Sterilizer identified, through dose response exposures, cycle exposure conditions that result in BI growth (BI fail conditions). This testing also demonstrated no growth pass conditions at both the half cycle and full cycle.

7. Summary of Clinical Performance Data

N/A – No clinical tests were conducted for this submission

8. Overall Performance Conclusion Statement

The results of the testing demonstrate that the Sterilucent SCBI is appropriate for monitoring the efficacy of the sterilization process in the Sterilucent PSD-85 Hydrogen Peroxide Sterilizer Lumen and Non-Lumen cycles. The proposed device and the predicate device utilize the same test organism which is appropriate for VHP sterilization processes. The proposed device and the predicate device are comprised of a similar design and materials. The proposed device and the predicate device have similar performance characteristics. The proposed device is substantially equivalent to the predicate device.